

EXHIBIT 11



Mallinckrodt plc Receives FDA Approval For XARTEMIS XR (oxycodone hydrochloride and acetaminophen) Extended-Release Tablets (CII)

***First and only extended-release oxycodone/acetaminophen medication approved for acute pain severe enough to require opioid treatment
Built on patented Mallinckrodt formulation platform***

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DUBLIN--(BUSINESS WIRE)--Mallinckrodt plc (NYSE: MNK) today announced that the U.S. Food and Drug Administration (FDA) has approved XARTEMIS™ XR (oxycodone hydrochloride and acetaminophen) Extended-Release Tablets (CII), previously known as MNK-795, for the management of acute pain severe enough to require opioid treatment and in patients for whom alternative treatment options (e.g., non-opioid analgesics) are ineffective, not tolerated or would otherwise be inadequate. XARTEMIS XR is the first and only extended-release oral combination of two clinically proven pain medications -- oxycodone and acetaminophen.

XARTEMIS XR has both immediate- and extended-release components: formulated to provide onset of pain relief in less than one hour and to allow twice daily dosing. The product's release profile combines Mallinckrodt's newly patented technology, including design, formulation, pharmacokinetic and release characteristics, and Depomed's advanced Acufarm® drug delivery technology.

The approval is based, in part, on the pivotal Phase 3 efficacy study conducted in an acute post-surgical pain model. XARTEMIS XR met the study's primary endpoint and showed statistically significant improvement in pain scores compared to placebo from baseline over 48 hours.

In addition to the efficacy study, Mallinckrodt conducted extensive lab testing and a human abuse liability study with XARTEMIS XR. Data from Mallinckrodt's studies related to the product were described in 15 scientific presentations at PAINWeek, held September 4-7, 2013. While the approved label for XARTEMIS XR does not include abuse-deterrent language, Mallinckrodt will continue working closely with the FDA to develop more data to characterize abuse-deterrence features of XARTEMIS XR and other products utilizing this technology platform. The company is conducting additional studies and will be providing additional data in the near future.

Pain that is uncontrolled or unmanaged results in ongoing and very significant costs to U.S. businesses in terms of lost productivity. In 2010, there were over 102 million surgical procedures ordered or performed at office visits.¹ That same year, there were 51 million inpatient surgeries performed.² The Institute of Medicine reported in 2011 that 80 percent of patients undergoing surgery experience postoperative pain. Of these, 88 percent report the pain is moderate, severe or extreme.³

"Acute pain doesn't last for only four to six hours, and neither should its treatment. With the extended-release profile of XARTEMIS XR, patients may not need to wake in the night to take a dose," said Nathaniel Katz, MD, MS, Adjunct Assistant Professor of Anesthesia at Tufts University School of Medicine. "A long-acting combination analgesic that can effectively deliver oxycodone and acetaminophen for acute pain patients experiencing pain throughout the day and night is a welcome addition to the treatment landscape."

"The FDA approval of XARTEMIS XR exemplifies Mallinckrodt's dedication to developing and providing new treatment options for people with pain," said Mark Trudeau, President and Chief Executive Officer of Mallinckrodt. "Mallinckrodt remains committed to continuing its work to develop innovative formulations for our product lines to help ensure access to appropriate pain treatment for the millions of patients suffering from acute pain, and we will continue to work closely with the FDA as we engage in further development programs for XARTEMIS XR and other products utilizing this technology platform."

Mallinckrodt is dedicated to providing quality medications for treatment of patients with pain and equally committed to fighting the problems of opioid misuse and abuse. The company supports a broad range of programs that encourage and support only appropriate use of pain medications, and we address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances, drug take-back programs and research into abuse-deterrent technologies.

To support the appropriate use of XARTEMIS XR and other Mallinckrodt products, the company:

- 1. Provides a range of educational resources for patients, physicians and pharmacists, including education initiatives validated by measurable outcomes.***

2. ~~Certifies its territory representatives following completion of robust education and training on all safe use initiatives for XARTEMIS XR.~~
3. **Addresses the safe and environmentally responsible disposal of unused XARTEMIS XR and other prescription medications** through a unique adsorption technology to render the drugs inactive and unusable.
4. **Maintains a comprehensive anti-diversion program** to detect potential misuse, abuse and diversion of Mallinckrodt products including XARTEMIS XR.

XARTEMIS™ XR (oxycodone HCl and acetaminophen) Extended-Release Tablets, for oral use, CII

INDICATIONS AND USAGE

XARTEMIS™ XR (oxycodone HCl and acetaminophen) Extended-Release Tablets (CII) is indicated for the management of acute pain severe enough to require opioid treatment and for which alternative treatment options are inadequate. Because of the risks of addiction, abuse, misuse, overdose, and death with opioids, even at recommended doses, reserve XARTEMIS XR for use in patients for whom alternative treatment options (e.g., non-opioid analgesics) are ineffective, not tolerated, or would be otherwise inadequate.

IMPORTANT RISK INFORMATION

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING

RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; NEONATAL OPIOID

WITHDRAWAL SYNDROME; and HEPATOTOXICITY

Addiction, Abuse, and Misuse

XARTEMIS XR exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing XARTEMIS XR, and monitor all patients regularly for the development of these behaviors or conditions.

Life-threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of XARTEMIS XR. Monitor for respiratory depression, especially during initiation of XARTEMIS XR or following a dose increase. Instruct patients to swallow XARTEMIS XR tablets whole; crushing, chewing, or dissolving XARTEMIS XR can cause rapid release and absorption of a potentially fatal dose of oxycodone.

Accidental Exposure

Accidental ingestion of XARTEMIS XR, especially in children, can result in a fatal overdose of oxycodone.

Neonatal Opioid Withdrawal Syndrome

Prolonged use of XARTEMIS XR during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Hepatotoxicity

XARTEMIS XR contains acetaminophen. Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the maximum daily limit, and often involve more than one acetaminophen-containing product.

CONTRAINDICATIONS

- XARTEMIS XR is contraindicated in patients with:
 - known hypersensitivity to oxycodone, acetaminophen, or any other component of this product.
 - significant respiratory depression.
 - acute or severe bronchial asthma or hypercarbia.
 - known or suspected paralytic ileus.

WARNINGS AND PRECAUTIONS

- XARTEMIS XR contains oxycodone, a Schedule II controlled substance. As an opioid, XARTEMIS XR exposes users to the risks of addiction, abuse, and misuse. Abuse or misuse of XARTEMIS XR by crushing, chewing, snorting, or injecting the dissolved product will result in the uncontrolled delivery of the oxycodone and can result in

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overdose and death. With intravenous abuse, the inactive ingredients in XARTEMIS XR can result in death, local tissue necrosis, infection, pulmonary granulomas, and increased risk of endocarditis and valvular heart injury. Parenteral drug abuse is commonly associated with transmission of infectious diseases such as hepatitis and HIV.

- Serious, life-threatening, or fatal respiratory depression has been reported with the use of opioids, even when used as recommended. While serious, life-threatening, or fatal respiratory depression can occur at any time during the use of XARTEMIS XR, the risk is greatest during the initiation of therapy or following a dose increase. Life-threatening respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients as they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients. In patients with significant chronic obstructive pulmonary disease or cor pulmonale, and patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or preexisting respiratory depression, XARTEMIS XR may decrease respiratory drive to the point of apnea.
- Hypotension, profound sedation, coma, respiratory depression, and death may result if XARTEMIS XR is used concomitantly with alcohol or other central nervous system (CNS) depressants.
- The risk of acute liver failure is higher in individuals with underlying liver disease and in individuals who ingest alcohol while taking acetaminophen.
- Rarely, acetaminophen may cause serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal.
- The respiratory depressant effects of narcotics and their capacity to elevate cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury, other intracranial lesions, or a pre-existing increase in intracranial pressure.
- Oxycodone may cause severe hypotension particularly in individuals whose ability to maintain blood pressure has been compromised by a depleted blood volume, or after concurrent administration with drugs which compromise vasomotor tone such as phenothiazines.
- Due to the potential for acetaminophen hepatotoxicity at doses higher than 4000 milligrams/day, XARTEMIS XR should not be used concomitantly with other acetaminophen-containing products.
- Hypersensitivity and anaphylaxis associated with use of acetaminophen have been reported. Clinical signs included swelling of the face, mouth, and throat, respiratory distress, urticaria, rash, pruritus, and vomiting.
- Due to characteristics of the formulation that cause the tablets to swell and become sticky when wet, consider use of an alternative analgesic in patients who have difficulty swallowing and patients at risk for underlying GI disorders resulting in a small gastrointestinal lumen. Instruct patients not to pre-soak, lick or otherwise wet XARTEMIS XR tablets prior to placing in the mouth, and to take one tablet at a time with enough water to ensure complete swallowing immediately after placing in mouth.
- Opioids diminish propulsive peristaltic waves in the gastrointestinal tract and decrease bowel motility. Oxycodone may cause spasm of the Sphincter of Oddi and should be used with caution in patients with biliary tract disease, including acute pancreatitis.
- Since the CYP3A4 isoenzyme plays a major role in the metabolism of XARTEMIS XR, drugs that alter CYP3A4 activity may cause changes in clearance of oxycodone which could lead to changes in oxycodone plasma concentrations.
- XARTEMIS XR may impair the mental and/or physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. The patient using this drug should be cautioned accordingly.

ADVERSE REACTIONS

- Serious adverse events may include respiratory depression and hepatotoxicity.
- Common adverse events include nausea, dizziness, headache, vomiting, constipation and somnolence.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Opioids cross the placenta and may produce respiratory depression and psychophysiologic effects in neonates. Prolonged use of XARTEMIS XR during pregnancy can result in withdrawal signs in the neonate, which can be life threatening.
- **Breast feeding:** Oxycodone is present in human milk and may result in accumulation and toxicities such as sedation and respiratory depression in some infants. Acetaminophen is present in human milk in small quantities.
- **Pediatrics:** Safety and effectiveness in pediatric patients under the age of 18 years have not been established.

See **Full Prescribing Information** for additional Important Risk Information including boxed warning.

About XARTEMIS™ XR

XARTEMIS XR is an extended-release oral formulation of oxycodone hydrochloride and acetaminophen with immediate-release and extended-release components. It is not interchangeable with other oxycodone/acetaminophen products because of differing pharmacokinetic profiles that affect the frequency of administration. XARTEMIS XR is a schedule II controlled substance.

About Mallinckrodt

Mallinckrodt is a global specialty pharmaceutical business that develops, manufactures, markets and distributes specialty pharmaceutical products and medical imaging agents. The company's Specialty Pharmaceuticals segment includes branded and specialty generic drugs and active pharmaceutical ingredients, and the Global Medical Imaging segment includes contrast media and nuclear imaging agents. Mallinckrodt has approximately 5,500 employees worldwide and a commercial presence in roughly 70 countries. The company's fiscal 2013 revenue totaled \$2.2 billion. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

References

¹CDC/NCHS, National Ambulatory Medical Care Survey. Accessed 2/25/2014.
http://www.cdc.gov/nchs/data/ahcd/namcs_summary/2010_namcs_web_tables.pdf.

²CDC, FastStats, accessed 2/25/14: <http://www.cdc.gov/nchs/fastats/insurg.htm>.

³Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Committee on Advancing Pain Research, Care, and Education; Institute of Medicine. 2011.

FORWARD-LOOKING STATEMENTS

Any statements contained in this communication that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements about future financial condition and operating results, economic, business, competitive and/or regulatory factors affecting our business. Any forward-looking statements contained herein are based on our management's current beliefs and expectations, but are subject to a number of risks, uncertainties and changes in circumstances, which may cause actual results or company actions to differ materially from what is expressed or implied by these statements. The factors that could cause actual future results to differ materially from current expectations include, but are not limited to, our ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration, our ability to obtain and/or timely transport molybdenum-99 to our technetium-99m generator production facilities, customer concentration, cost-containment efforts of customers, purchasing groups, third-party payors and governmental organizations, our ability to successfully develop or commercialize new products, our ability to protect intellectual property rights, competition, our ability to integrate acquisitions of technology, products and businesses, product liability losses and other litigation liability, the reimbursement practices of a small number of large public or private issuers, complex reporting and payment obligation under healthcare rebate programs, changes in laws and regulations, conducting business internationally, foreign exchange rates, material health, safety and environmental liabilities, litigation and violations, information technology infrastructure and restructuring activities. These and other factors are identified and described in more detail in the "Risk Factors" section of Mallinckrodt's Annual Report on Form 10-K for the fiscal year ended September 27, 2013 and in subsequent filings. We disclaim any obligation to update these forward-looking statements other than as required by law.

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